

BEFORE THE
OFFICE OF ADMINISTRATIVE HEARINGS
STATE OF CALIFORNIA

In the Matter of:

A.C.,

Claimant,

vs.

SAN DIEGO REGIONAL CENTER,

Service Agency.

OAH No. 2011031154

DECISION

Administrative Law Judge Alan R. Alvord, State of California, Office of Administrative Hearings, heard this matter in San Diego, California, on June 13, 2011.

Ron House, Attorney at Law, San Diego Regional Center, represented the San Diego Regional Center.

N.V., claimant's mother, represented the claimant.

The record was held open for submission of additional evidence. Claimant's exhibits 36-50 were received on June 16, 2011. The service agency's exhibit 51 was received on June 24, 2011.¹ Claimant requested and was granted additional time to respond to Exhibit 51. The record held open and the matter was submitted on July 12, 2011.

ISSUE

Is the service agency required to fund 32 hours of intensive behavioral intervention services to help claimant learn to swallow pills?

¹ Claimant's objection to Exhibit 51 on the basis that it is unsigned is sustained. Exhibit 51 is received as the service agency's argument, but is not received as testimony.

FACTUAL FINDINGS

Background Information

1. Claimant A.C. is a five-year-old boy who lives with both of his parents. He is their only child. He qualifies for services under the Lanterman Developmental Disabilities Act due to a diagnosis of autistic disorder.

2. Claimant began receiving occupational therapy, speech therapy and infant education services before age 3 under the Early Intervention Program. He qualified for Lanterman Act services at age 3. The service agency funds 10 hours per week of direct behavioral instruction, which is currently provided by the Center for Autism and Related Disorders, Inc. (CARD), a regional center vendor.

3. Claimant is non-verbal, although he is developing some words. He communicates mostly using hand gestures and signals or an electronic communication device. He is allergic to many foods, including dairy, soy, wheat, gluten, peanuts, tree nuts, shellfish, chicken, eggs, and other foods.² He also has asthma. His oral-motor skills for eating and swallowing are described as normal for his age.

4. Claimant's parents assert that he suffers from gastrointestinal illnesses that require long term, daily medication and dietary supplements. Claimant's maternal grandparents are both physicians in Mexico. They are his primary care doctors. Claimant also sees Robert W. Barr, M.D., a pediatrician, in Poway, California, and James J. Bradstreet, M.D. (Dr. Bradstreet), a physician with offices in Florida and Irvine, California.

5. Claimant's parents prepare all of his meals. Getting claimant to take medication and supplements has been very stressful for the family. He can not swallow pills. They have tried various techniques for opening the capsules and making liquid suspensions or mixing the contents in food. The nature of the medications and supplements do not permit creating batches of liquid suspensions ahead of time. To be effective, the medications and supplements must be converted to liquid and consumed immediately. They have tried various mixing compounds to convert the medicines and supplements to liquid. Claimant's parents believe he has become allergic to the most common and successful mixing agents.

As with many children with autism, claimant demonstrates an increased sensitivity to the tastes and textures of foods and liquids. His parents have had to restrain him while guiding him physically to swallow the syrups or medicated food. This process resulted in inaccurate dosing and an increase in claimant's aggressive behavior toward himself and

² Claimant's mother states that he is allergic to over 88 foods. The service agency medical staff disagrees with the methods used to assess these allergies and with the number of allergies claimant has. The service agency does not dispute that claimant has many food allergies.

others. On one occasion after a struggle over medication, claimant began chewing his own finger, causing a lesion. After this event, his parents asked the service agency for help.

Claimant's parents believe a short-term behavioral program to teach claimant to swallow pills will facilitate his ability to take medication and supplements, and will improve his quality of life.

Request to the Service Agency; Response

6. Claimant's mother contacted his behavioral services provider, CARD, and requested a proposal for CARD to provide behavioral intervention training to teach claimant to swallow pills. On February 7, 2011, CARD prepared a Medical Facilitation Intake Evaluation outlining a plan to teach the pill swallowing skill to claimant. CARD proposed a 32 hour intensive training program over four months to train claimant to take three medications/supplements: "Niastatin" (Nystatin), Learner's Edge, and "zin" (zinc). (Exhibit 28). At the hearing, claimant's mother amended the medication list to include fluconazole, Learner's Edge, HLC Probiotic (a digestive aid supplement), EpiCor (a supplement marketed to strengthen the immune system) and Digest Right Enzymes (a supplement marketed as having been formulated for children to help with digestion). (Exhibit 32)³

7. The service agency reviewed the original request through interdisciplinary team meetings. The team concluded that it would not be appropriate to include the pill swallowing training in the 10 hours per week of behavioral services claimant already receives because it would detract from other skills claimant is developing. The team determined that the pill swallowing skill problem is related to claimant's developmental disability.

The team also concluded that the behavioral intervention program to teach pill swallowing skills to an autistic child has support in peer reviewed literature. Several studies reported modest success of behavioral intervention techniques to teach pill swallowing to children with autism. The team therefore concluded that this intervention is evidence-based.

The team next considered whether pill swallowing training for claimant is developmentally appropriate. The team reviewed literature and concluded that typical children acquire pill swallowing skills between the ages of 6 and 11. The service agency interdisciplinary team concluded that claimant is not developmentally delayed in his pill swallowing skill since he is five years old and typical children acquire this skill between the ages of 6 and 11.

³ The service agency's medical staff was given time during the hearing to review the revised list of medications and supplements. The new information did not change the service agency's decision to deny claimant's request for pill swallowing behavioral intervention services.

As a final step in its interdisciplinary review, the team concluded that the diagnosis of allergies and gastrointestinal illnesses, and the proposed treatment course using supplements and medications, was not evidence-based. The service agency's interdisciplinary team believed it was prohibited by law from funding services that are not evidence-based. For this reason, the service agency denied the request.

8. On March 7, 2011, the service agency issued its notice of proposed action denying the request for services.

Claimant filed a timely request for a fair hearing.

Does Claimant Have a Medical Condition Requiring Treatment with Fluconazole?

9. Claimant offered a letter (Exhibit 17) from Dr. Bradstreet. Dr. Bradstreet is licensed to practice medicine in California.⁴ Dr. Bradstreet's letter stated claimant has a diagnosis of autism. His letter stated that claimant's current treatment includes daily doses of Diflucan⁵ and Learner's Edge supplement.

10. Dr. Bradstreet's letterhead indicates he works for Creation's Own Corp., which markets the supplement Learner's Edge as a treatment for autism. Learner's Edge is only available in capsule form.

11. Claimant's parents believe claimant has a gastrointestinal illness involving high levels fungus in his digestive system. However, Dr. Bradstreet's letter did not express a diagnosis of any gastrointestinal illness. Dr. Bradstreet's letter only mentions a diagnosis of autism. Claimant asserted that several blood test results supported the diagnosis of intestinal fungus. The blood test results, by themselves, may not be relied upon to establish the presence of a fungal infection without medical expert testimony interpreting the results.

12. The evidence did not establish that claimant has a medical condition requiring treatment with fluconazole. While Dr. Bradstreet apparently prescribed fluconazole for claimant, the only diagnosis Dr. Bradstreet expressed is autism. There was no evidence fluconazole is an accepted medical treatment for autism.

13. Even if the evidence had supported a diagnosis involving a digestive fungal infection, the evidence did not establish that the systemic anti-fungal medication fluconazole is an accepted treatment for this condition. The service agency's medical expert, Joan Reese,

⁴ The service agency's physician testified that she did "not believe" Dr. Bradstreet is licensed in California. Official notice under Government Code section 11515 is taken of the Medical Board of California's Website information, accessed at www.medbd.ca.gov/lookup.html, which states that Dr. Bradstreet is licensed to practice in California.

⁵ Diflucan is a brand name for fluconazole, a systemic antifungal antibiotic used to treat infections caused by fungus.

M.D., testified that the use of fluconazole to treat digestive fungus is not accepted medical practice. Claimant did not offer any medical expert testimony to the contrary.

Does Claimant have a Medical Condition Requiring Treatment with Digestive Supplements?

14. Claimant's parents would like to give him the nutritional supplement compounds Epi-cor, Digest Right Enzymes and HLC Probiotic to help with his digestion. Each of these supplements is available without a prescription.

15. Claimant offered a letter from Xenia Hom, M.D., a physician with the gastroenterology department at Rady Children's Hospital in San Diego, California. Dr. Hom stated that she prescribes "probiotics to some patients with specific diagnoses that have been shown with evidence based studies to respond to this as treatment." Dr. Hom's letter did not state that she has prescribed probiotic supplements for claimant or that he has a specific diagnosis that has been shown with evidence based studies to respond to probiotic treatment.

16. Claimant also offered a letter from David J. Getoff, "naturopath" and "board certified clinical nutritionist." Mr. Getoff's letterhead indicates he is licensed as a nutritionist in the State of New York and as a naturopath in North Carolina. There was no evidence Mr. Getoff is licensed in California.

Mr. Getoff's letter stated that claimant's "current medical treatment includes a number of supplements including pills or capsules: EpiCor, HLC probiotic," and that he has recommended claimant take EpiCor and HLC probiotic.

17. The evidence did not establish that any physician has recommended or prescribed digestive supplements for claimant. The only recommendation that claimant take these compounds in the evidence was given by Mr. Getoff. Mr. Getoff's recommendation is insufficient to support a finding that claimant has a medical condition requiring treatment with digestive supplements.

18. Even if the evidence established a medical condition requiring treatment with digestive supplements, the evidence did not establish that such treatment is clinically determined or scientifically proven to be effective or safe or that such treatment for claimant's specific condition is a general physician practice.

19. Claimant offered several published studies showing the effectiveness of different compounds as digestive aids. These studies, by themselves and without medical expert analysis, were insufficient to establish that such treatment for children is scientifically proven to be effective and safe.

Does Claimant Have a Medical Condition Requiring Treatment with Learner's Edge Supplement?

20. The supplement Learner's Edge has been prescribed by claimant's physician, Dr. Bradstreet, to treat or help ameliorate the effects of claimant's autistic disorder.

21. The evidence established that Learner's Edge was prescribed by claimant's physician specifically due to claimant's autistic disorder.

Is Learner's Edge Clinically Determined or Scientifically Proven to be Effective and Safe as a Treatment for Autism?

22. Claimant did not offer any scientific studies supporting the contention that treatment with Learner's Edge is proven to be effective for autism. Official notice is taken of marketing materials for Learner's Edge (accessed online at <http://www.thedocsorders.com/collections/kids/products/learners-edge>) which state that Lerner's Edge "provides a combination of ingredients designed to support neurological development and function in children."

23. Dr. Reese testified that the service agency was unable to find any peer-reviewed scientific studies supporting the effectiveness or safety of Learner's Edge and that it is not general physician practice to prescribe supplements to children with autism.

24. The evidence did not establish that treatment with Learner's Edge is scientifically proven or clinically determined to be effective or safe for claimant.

LEGAL CONCLUSIONS

1. In enacting the Lanterman Developmental Disabilities Services Act (Lanterman Act), section 4500 et seq., the Legislature accepted its responsibility to provide for the needs of developmentally disabled individuals, and recognized that services and supports should be established to meet the needs and choices of each person with developmental disabilities. (Welf. & Inst. Code, § 4501.)

2. The Lanterman Act gives regional centers a critical role in the coordination and delivery of services and supports for persons with disabilities. (Welfare and Institutions Code sections 4620 et seq.) Regional centers are responsible for developing and implementing individualized program plans (IPPs), for taking into account consumer needs and preferences, and for ensuring service cost-effectiveness. (Welf. & Inst. Code, §§ 4646, 4646.5, 4647, and 4648.)

3. Welfare and Institutions Code section 4512, subdivision (b), defines the services and supports that may be funded, and sets forth the process through which such are identified, namely, the IPP process, a collaborative process involving consumer and service agency representatives:

Services and supports for persons with developmental disabilities means specialized services and supports or special adaptations of generic services and supports directed toward the alleviation of a developmental disability or toward the social, personal, physical, or economic habilitation or rehabilitation of an individual with a developmental disability, or toward the achievement and maintenance of independent, productive, normal lives. The determination of which services and supports are necessary for each consumer shall be made through the individual program plan process. The determination shall be made on the basis of the needs and preferences of the consumer, or where appropriate, the consumer's family, and shall include consideration of a range of service options proposed by individual program plan participants, the effectiveness of each option in meeting the goals stated in the individual program plan, and the cost-effectiveness of each option

4. Welfare and Institutions Code section 4648, subdivision (a)(15) provides that:

Notwithstanding any other provision of law or regulation to the contrary, effective July 1, 2009, regional centers shall not purchase experimental treatments, therapeutic services, or devices that have not been clinically determined or scientifically proven to be effective or safe or for which risks and complications are unknown. Experimental treatments or therapeutic services include experimental medical or nutritional therapy when the use of the product for that purpose is not a general physician practice. For regional center consumers receiving these services as part of their individual program plan (IPP) or individualized family service plan (IFSP) on July 1, 2009, this prohibition shall apply on August 1, 2009.

5. The evidence did not establish that claimant has a condition that requires treatment with fluconazole or digestive supplements. The evidence established that a physician has prescribed Learner's Edge supplement for claimant's autism, but did not establish that such treatment is clinically or scientifically proven to be safe and effective.

6. The service agency argues that it is precluded from funding pill swallowing training for claimant where the purpose for the training is to facilitate treatments that are experimental or not clinically proven. Claimant argues that the intended purpose for the pill swallowing skill is irrelevant, that the Lanterman Act authorizes funding of this type of life skill, that the service agency acknowledges that pill swallowing training itself is not

experimental, and that the service agency is over-reaching by conflating the restrictions on funding experimental therapies with the teaching of a necessary life skill.

7. Claimant is correct that pill swallowing training for autistic children is not experimental and that a regional center is not directly precluded by section 4648 from funding this type of service. However, as applied to claimant's specific needs, claimant's request for pill swallowing training as a general life skill is premature. It has not yet been established that claimant is developmentally delayed in acquisition of the pill swallowing skill. The service agency can not be required to fund the development of pill swallowing skills unless it is first established that claimant has been unable to acquire the skill on his own. Since pill swallowing is acquired by typical children between the ages of 6 and 11, it is too early to tell whether claimant will or will not be able to learn to swallow pills without intervention.

8. There may be circumstances where a particular consumer's medical needs require pill swallowing skills earlier than the normal developmental age range for acquiring the skill. However, the evidence did not establish that claimant's particular medical or developmental needs require pill swallowing at this time.

9. Claimant's parents are understandably trying to do all they can to improve claimant's health and quality of life as he grows and develops. The evidence did not establish, however, a legal basis to require the service agency to fund pill swallowing training for claimant at this time.

ORDER

Claimant's appeal of the regional center's decision not to fund pill swallowing training for claimant is denied.

Dated: July 25, 2011

ALAN R. ALVORD
Administrative Law Judge
Office of Administrative Hearings

NOTICE

This is the final administrative decision. Both parties are bound by this decision. Either party may appeal this decision to a court of competent jurisdiction within the State of California.